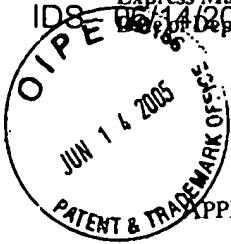


06-15-03

JFW

Express Mail Label No.: EV 475171185 US  
Date of Deposit: June 13, 2005

Docket No.: 18989-032



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS : Bunn, et al.  
SERIAL NUMBER : 10/772,076 EXAMINER : Yong D. Pak  
FILING DATE : February 3, 2004 ART UNIT : 1652  
FOR : COMPOSITIONS AND METHODS OF TREATING DIABETES

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

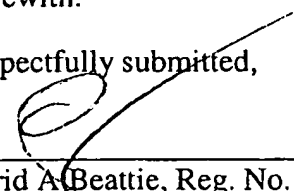
Transmitted herewith for filing in the above-referenced patent application are the following documents:

1. Supplemental Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (2 pages), in duplicate;
3. Copies of cited references B3; C4-21; and
4. Return postcard.

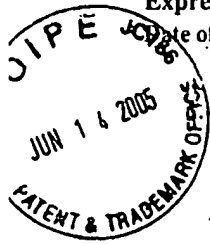
If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617-542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 18989-032. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

  
\_\_\_\_\_  
Ingrid A. Beattie, Reg. No. 42,306  
Cynthia A. Kozakiewicz, Reg. No. 42,764  
Attorneys for Applicants  
c/o MINTZ, LEVIN  
Address all written correspondence to  
**Customer no.: 30623**  
Tel: (617) 542-6000

Date: June 13, 2005



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS : Bunn, et al.  
SERIAL NUMBER : 10/772,076 EXAMINER : Yong D. Pak  
FILING DATE : February 3, 2004 ART UNIT : 1652  
FOR : COMPOSITIONS AND METHODS OF TREATING DIABETES

**Mail Stop Amendment**  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Supplemental Information Disclosure Statement is being filed before the mailing date of a first Office Action based on the merits in the above-identified case. Accordingly, no fee or certification is believed due. By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A1-A3 are not submitted.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and sign the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Supplemental Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

APPLICANTS: **Bunn et al.**  
U.S.S.N.: **10/772,076**

Notwithstanding any statements by the Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19898-032.

Respectfully submitted,



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Ingrid A Beattie, Reg. No. 42,306  
Cynthia A. Kozakiewicz, Reg. No.42,764  
Attorneys for Applicants  
c/o MINTZ, LEVIN  
Address all written correspondence to  
**Customer no.: 30623**  
Tel: (617) 542-6000

Date: June 13, 2005

TRA 2023019v1



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Approved for use through 9/30/00. OMB 0651-0031  
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE  
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Modified Form 1449/PTO				Application Number		10/772,076	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Filing Date		February 3, 2004	
				First Named Inventor		Bunn	
				Group Art Unit		1652	
				Examiner Name		Yong D. Pak	
				Attorney Docket Number		18989-032	
<b>U.S. PATENT DOCUMENTS</b>							
Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
MN	*A1	3,625,214	12/07/71	Higuchi	128	260	
MN	*A2	4,789,734	12/06/88	Pierschbacher	530	395	
MN	*A3	4,925,673	05/15/90	Steiner et al.	424	455	
<b>U.S. PUBLISHED APPLICATION DOCUMENTS</b>							
Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate
<b>FOREIGN PATENT DOCUMENTS</b>							
Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No		
MN	B3	WO 89/07136	WHITEHEAD INSTITUTE FOR BIOCHEMICAL RESEARCH; HOWARD HUCHES MEDICAL INSTITUTE	08/10/89			
<b>OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS</b>							
Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.					
MN	C4	GENBANK Accession No. AF169803 (2000)					
	C5	GENBANK Accession No. AAF04812 (2000)					
	C6	GENBANK Accession No. XM229210					
	C7	GENBANK Accession No. XP229210					
	C8	GENBANK Accession No. P56395 (2004)					
	C9	GENBANK Accession No. P00173 (2004)					
	C10	GENBANK Accession No. P20070 (2005)					
	C11	GENBANK Accession No. AL034347 (2005)					
	C12	Gregoriadis <i>Drug Carriers Biol. Med.</i> , pp. 287-341 (Academic Press) (1979)					
	C13	Johnson et al. <i>J. Biol. Chem.</i> , 273(52):35147-35152 (1998)					
	C14	Kotani et al. <i>Anal. Biochem.</i> , 284(1):65-69 (2000)					
	C15	Kotin et al. <i>Proc. Natl. Acad. Sci. USA</i> , 87:2211-2215 (1990)					
	C16	Leiter et al. <i>Am. J. Pathol.</i> , 128(2):380-383 (1987)					
MN	C17	Lu et al. <i>Abstracts of the Meeting on Gene Therapy</i> , Sept. 22-26, 1992, Cold Spring Harbor Laboratory, Cold Spring Harbor, New York, Abstract, page 66.					

MN	C18	Morsy et al. <i>J. Cell. Biochem.</i> , Suppl. 17E, pp. 226, Abstract SZ109 (1993)
MN	C19	Rosenberg et al. <i>N. Engl. J. Med.</i> , 323(9):570-578 (1990)
MN	C20	Waddington et al. <i>Anal. Biochem.</i> , 292(2):234-244 (2001)
	<del>C21</del>	<del>Zhu et al. <i>Proc. Natl. Acad. Sci. USA</i>, 96(26):14742-14747 (1999)</del> duplicate

\* By the waiver of 37 CFR 1.98(a)(2)(i) copies of the U.S. Patents A1-A3 are not submitted.

Examiner Signature	Marcia S. Noble <small>Digitally signed by Marcia S. Noble DN: cn=Marcia S. Noble, o=US PTO, ou=AU 1632, email=Marcia.Noble@uspto.gov Date: 2007.02.11 01:00:51 -0500</small>	/Marcia Noble/	Date Considered	02/11/2007
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

TRA 1983916v1

12-03-04

FW

IDS - 12/02/2004  
Express Mail Label No.: EV 392126175 US  
Date of Deposit: December 2, 2004

Docket No.: 18989-032



**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

APPLICANTS : Bunn, et al.  
SERIAL NUMBER : 10/772,076 EXAMINER : Not Yet Assigned  
FILING DATE : February 3, 2004 ART UNIT : 1651  
FOR : COMPOSITIONS AND METHODS OF TREATING DIABETES

**MAIL STOP AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**TRANSMITTAL LETTER**

Transmitted herewith for filing in the above-referenced patent application are the following documents:

1. Information Disclosure Statement (2 pages), in duplicate;
2. Modified Form 1449/PTO (1 page), in duplicate;
3. Copies of cited references B1-2; C1-3; and
4. Return postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617-542-6000, Boston, Massachusetts.

The Commissioner is authorized to charge any fees that may be due, or to credit any overpayment, to the undersigned's account, Deposit Account No. 50-0311 Ref. No. 18989-032. A duplicate copy of this transmittal letter is enclosed herewith.

Respectfully submitted,

Ingrid A Beattie, Reg. No. 42,306  
Cynthia A. Kozakiewicz, Reg. No. 42,764  
Attorneys for Applicants  
c/o MINTZ, LEVIN  
Address all written correspondence to  
Customer no.: 30623  
Tel: (617) 542-6000

Dated: December 2, 2004

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**



APPLICANTS : Bunn, et al.

SERIAL NUMBER : 10/772,076

EXAMINER : Not Yet Assigned

FILING DATE : February 3, 2004

ART UNIT : 1651

FOR : COMPOSITIONS AND METHODS OF TREATING DIABETES

**Mail Stop Amendment**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed on the attached modified Form PTO-1449, as well as copies of the listed documents.

This Information Disclosure Statement is being filed within three months of the mailing date of the International Search Report for PCT/US2004/003035, mailed September 22, 2004 that corresponds to the above-identified application. Accordingly, no fee or certification is believed due.

It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and sign the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

By submitting this Information Disclosure Statement, the Applicants make no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

APPLICANTS: **Bunn et al.**  
U.S.S.N.: **10/772,076**

Notwithstanding any statements by the Applicants, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested.

Please charge any fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 19898-032.

Respectfully submitted,



---

Ingrid A Beattie, Reg. No. 42,306  
Cynthia A. Kozakiewicz, Reg. No. 42,764  
Attorneys for Applicants  
c/o MINTZ, LEVIN  
Address all written correspondence to  
**Customer no.: 30623**  
Tel: (617) 542-6000

Dated: December 2, 2004

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<b>Modified Form 1449/PTO</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)	<b>Application Number</b>	10/772,076
	<b>Filing Date</b>	February 3, 2004
	<b>First Named Inventor</b>	Bunn
	<b>Group Art Unit</b>	1651
	<b>Examiner Name</b>	Not Yet Assigned
	<b>Attorney Docket Number</b>	18989-032

**U.S. PATENT DOCUMENTS**

Exam Initials	Cite No.	U.S. Patent Document No.	Issue Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate

**U.S. PUBLISHED APPLICATION DOCUMENTS**

Exam Initials	Cite No.	U.S. Published Application No.	Published Date	Name of Patentee(s) or Applicant(s)	Class	Sub Class	Filing Date If Appropriate

**FOREIGN PATENT DOCUMENTS**

Exam Initials	Cite No.	Foreign Patent Document Office Number	Name of Patentee(s) or Applicant(s)	Date of Publication	Translation Yes No
MN	B1	WO 01/44448 A2	INCYTE GENOMICS, INC.	06/21/01	
MN	B2	WO 03/087399 A1	BIOVIT-RUM AB	10/23/03	

**OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS**

Exam Initials	Cite No.	Name of Author, Title (when appropriate), Publication, Volume, Page(s), Date, Etc.
MN	C1	Barber et al. <i>Protein Expression and Purification</i> , 23:348-358 (2001)
MN	C2	Zhu, et al. <i>PNAS</i> , 96(26):14742-14747 (1999)
MN	C3	International Search Report for PCT/US2004/003035, mailed on September 22, 2004.

\* a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_\_\_\_, filed \_\_\_\_\_, and relied upon for an earlier filing date under 35 U.S.C. §120 (continuation, continuation-in-part, and divisional applications).

<b>Examiner Signature</b>	Marcia S. Noble <small>Digitally signed by Marcia S. Noble DN: cn=Marcia S. Noble, o=US, ou=USPTO, ou=AU 1632, email=Marcia.Noble@uspto.gov Date: 2007.02.11 01:02:56 -0500</small>	<b>Date Considered</b>	02/11/2007
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**EXAMINER:** Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.